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| APPLICATION NO.                                | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO |
|--|-------------|----------------------|-------------------------|-----------------|
| 10/075,703                                     | 02/14/2002  | Steven I. Dworetzky  | CT-2614-NP              | 8374            |
| 7590 07/19/2004                                |             |                      | EXAMINER                |                 |
| Stephen B. Davis                               |             |                      | MCKENZIE, THOMAS C      |                 |
| BRISTOL-MYERS SQUIBB COMPANY Patent Department |             |                      | ART UNIT                | PAPER NUMBER    |
| P. O. Box 4000                                 |             |                      | 1624                    |                 |
| Princeton, NJ 08543-4000                       |             |                      | DATE MAILED: 07/19/2004 |                 |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.   | Applicant(s)   |  |  |  |  |
|---|---|--|--|--|--|--|
|   | 10/075,703  | DWORETZKY ET AL.   |  |  |  |  |
| Office Action Summary   | Examiner  | Art Unit   |  |  |  |  |
|   | Thomas McKenzie, Ph.D.  | 1624   |  |  |  |  |
| The MAILING DATE of this communication a  | ppears on the cover sheet with t  | he correspondence address  |  |  |  |  |
| Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  |   |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REF THE MAILING DATE OF THIS COMMUNICATION  - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a relif NO period for reply is specified above, the maximum statutory perions are really within the set or extended period for reply will, by state Any reply received by the Office later than three months after the main earned patent term adjustment. See 37 CFR 1.704(b). | N. 1.136(a). In no event, however, may a reply to the statutory minimum of thirty (30 and will apply and will expire SIX (6) MONTHS tute. cause the application to become ABAND | be timely filed  )) days will be considered timely, from the mailing date of this communication.  )ONED (35 U.S.C. § 133). |  |  |  |  |
| Status  |   |  |  |  |  |  |
| 1) Responsive to communication(s) filed on 18   | May 2004.   |  |  |  |  |  |
| This action is <b>FINAL</b> . 2b) ☐ This action is non-final.   |   |  |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |   |  |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.   |   |  |  |  |  |  |
| Disposition of Claims   |   |  |  |  |  |  |
| 4)⊠ Claim(s) <u>1,2,4-10 and 17</u> is/are pending in the   | he application.   |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |   |  |  |  |  |  |
| 5) Claim(s) is/are allowed.   |   |  |  |  |  |  |
| 6)⊠ Claim(s) <u>1,2,4-10 and 17</u> is/are rejected.  |   |  |  |  |  |  |
| 7) Claim(s) is/are objected to.   |   |  |  |  |  |  |
| 8) Claim(s) are subject to restriction and  | d/or election requirement.  |  |  |  |  |  |
| Application Papers  |   |  |  |  |  |  |
| 9)☐ The specification is objected to by the Examiner.   |   |  |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  |   |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |   |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |   |  |  |  |  |  |
| Priority under 35 U.S.C. § 119  |   |  |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |   |  |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:  |   |  |  |  |  |  |
| 1. Certified copies of the priority documents have been received.   |   |  |  |  |  |  |
| 2. Certified copies of the priority docume  |   | lication No  |  |  |  |  |
| 3. Copies of the certified copies of the p  | riority documents have been rec   | ceived in this National Stage  |  |  |  |  |
| application from the International Bure   |   |  |  |  |  |  |
| * See the attached detailed Office action for a l   | ist of the certified copies not rec   | ceived.  |  |  |  |  |
|   |   |  |  |  |  |  |
| Attachment(s)   | . 🗂   |  |  |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 4) 🛄 Interview Sum<br>Paper No(s)/M   | lail Date  |  |  |  |  |
| <ul> <li>2) Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/Paper No(s)/Mail Date 11/10/03.</li> </ul>   | es 🗍  | mal Patent Application (PTO-152)   |  |  |  |  |

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## **DETAILED ACTION**

1. This action is in response to amendments filed on 5/18/04. Applicant has amended claims 1, 2, and 4. Applicant has canceled claims 3 and 11-16. Claim 17 is new. There are ten claims pending and ten under consideration. Claims 1, 2, 4, 5, and 17 are compound claims. Claims 6-10 are use claims. This is the second action on the merits. The application concerns some 3-fluoro-2-oxidole compounds and uses thereof.

Response to Amendment

2. Applicants' amendments and cancellation of claims 12-16 overcome the objections made in points #3, #4, and #7 of the previous office action. Applicants' remarks and the amendments to claims 1 and 2, clarify the status of the OR<sup>5</sup> radical. The indefiniteness rejection made in point #8 is withdrawn. Applicants' new claims to salts only overcome the enablement rejection made in point #9.

Claim Objections

3. Objection is made to claim 2 under 37 CFR 1.75 as being a duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The phrases "hyperpolarizing neuron that fire before or during a migraine headache" and "preventing abnormal synchronous neuronal firing associated with migraine" are

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statements of intent. These are purely mental acts with no physical consequences.

Thus, claim 2 is a compound claim with the same limitations as claim 1.

- 4. Claim 2 is objected to because of the following informalities: There are two periods at the end of this claim. Appropriate correction is required.
- 5. Objection is made to claim 17 under 37 CFR 1.75 as being a duplicate of claim 4. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). These claims depend upon different parent claims but are claiming the same compound. Thus, claim 17 is a compound claim with the same limitations as claim 4.

## **Double Patenting**

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). A

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timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4-10 remain rejected and claim 17 is newly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 9-12 of U.S. Patent No. 6,469,042. Although the conflicting claims are not identical, they are not patentably distinct from each other because after restriction, Applicants elected subject matter is identical in scope to that claimed in the first claim of the reference, with the exception of the presently taught salts, solvates etc. Lines 38-49, column 1 and lines 30-53, column 13 of the reference teach that KCNQ related diseases are associated with various migraine conditions.

Applicants state that a terminal disclaimer has been filed. To date, none has been received in the case. Please note that Applicants' transmittal of the present amendments apparently was filed on 2/9/04 but referred to an incorrect Application number.

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## Conclusion

- 7. Applicant's amendment necessitated the new ground(s) of objection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.
- 8. Information regarding the status of an application should be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). Please

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direct general inquiries to the receptionist whose telephone number is (703) 308-1235.

9. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (571) 272-0670. The FAX number for amendments is (703) 872-9306. The PTO presently encourages all applicants to communicate by FAX. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, please contact please contact James O. Wilson, acting SPE of Art Unit 1624, at (571)-272-0661.

Thomas C. McKenzie, Ph.D

Patent Examiner Art Unit 1624

TCMcK/me